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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,586	07/03/2001	Valerie L. Gerlach	15966-638CIP (Cura-138CIP	2872

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Ivor R. Elrifi
Mintz, Levin, Cohn, Ferris,
Glovsky and Popeo, P.C.
One Financial Center
Boston, MA 02111

EXAMINER	
LI, RUIXIANG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 04/04/2002 9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/898,586	Applicant(s) GERLACH ET AL.	
	Examiner Ruixiang Li	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-79* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 29, 32, 44-47, 67, and 70, drawn to polypeptides, compositions and kits comprising the polypeptides, classified in class 530, subclass 395, and class 514, subclass 8.

II. Claims 5-14, 30, 33, 48-57, 68, and 71, drawn to nucleic acid molecules, vectors, host cells, compositions and kits comprising the nucleic acid molecule, classified in class 536, subclass 23.5 and class 435, subclass 320.1, 325, and class 514, subclass 44.

III. Claims 15-17, 31, 34, 58, 69, and 72, drawn to antibodies, compositions and kits comprising the antibodies, classified in class 530, subclass 387.9, and class 424, subclass 134.1.

IV. Claims 18 and 59, drawn to a method for detecting polypeptides, classified in class 435, subclass 7.1.

V. Claims 19 and 60, drawn to a method for detecting a nucleic acid molecule, classified in class 435, subclass 6.

VI. Claims 20 and 61, drawn to a method for identifying polypeptide-binding agents, classified in class 435, subclass 7.1.

VII. Claims 21 and 62, drawn to a method for identifying a potential agent for use in treatment of a pathology, classified in class 436, subclass 501.

VIII. Claims 22 and 63, drawn to a method for modulating polypeptide activity, classified in class 435, subclass 7.1.

IX. Claims 23, 24, 35, 42, 64, 73, and 78, drawn to a method of treating a pathology with polypeptides, classified in class 514, subclass 8.

X. Claims 25, 26, 36, and 65, drawn to a method of treating a disorder with nucleic acid molecules, classified in class 514, subclass 44.

XI. Claims 27, 28, 37, 43, 66, and 79, drawn to a method of treating a disorder with antibodies, classified in class 424, subclass 130.1.

XII. Claims 38, 39, 74, and 75, drawn to a method for screening for a modulator of activity or of latency or predisposition to a pathology associated with polypeptides, classified in class 436, subclass 501.

XIII. Claims 40 and 76, drawn to a method for determining the presence of or predisposition to a disease associated with altered levels of the polypeptides by measuring the level of expression of the polypeptide in a sample, classified in class 435, subclass 7.1.

XIV. Claims 41 and 77, drawn to a method for determining the presence of or predisposition to a disease associated with altered levels of the polypeptides by measuring the amount of the nucleic acid in a sample,, classified in class 435, subclass 6.

2. The inventions are distinct, each from the other for the following reasons. Inventions I, II, and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation,

different functions, or different effects (MPEP §806.04, MPEP §808.01). In the instance case, the different inventions are drawn to completely different products, a nucleic acid molecule, polypeptides, and an antibody. These molecules have completely different structures and biological functions which are not interchangeable and which require non-cohesive searches and considerations.

3. Inventions IV-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). In the instance case the different inventions are drawn to completely different methods each having completely different method steps, using different compositions, and having completely different outcomes. First, the method of detecting polypeptides or a nucleic acid molecule will not identify polypeptide-binding agents, or modulators of polypeptide expression and activity. Nor will it provide any information regarding the methods of treatment using a polypeptide, a nucleic acid molecule, or an antibody, or disease diagnosis. Secondly, the method for identifying polypeptide-binding agents or modulators of polypeptide expression or activity will not provide any information on methods of detect polypeptides or nucleic acids, or a method for modulating polypeptide activity. Nor will it provide information regarding disease diagnosis or treatment. Third, the methods of disease diagnosis or treatment will not provide information on the methods of detecting a nucleic acid molecule, polypeptides, or the methods of identifying polypeptide-binding agents or an agent that modulates polypeptide expression or activity. Thus, all the methods are exclusive.

4. Invention I is related to IV, VI-IX, XII, and XIII as product and process of use. The invention can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05 (h)). In the instance case, the peptide may be used in a materially different process such as immunization of animals to produce antibodies.
5. Invention II is related to Inventions V, VII, X, and XIV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05 (h)). In the instance case, the nucleic acid may be used in a materially different process such as production of peptides.
6. Invention III is related to Inventions IV, VI, XI, and XIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05 (h)). In the instance case, the antibody may be used in a materially different process such as protein purification.
7. Invention I is unrelated to Inventions V, X, XI, and XIV because Invention I is drawn to polypeptides whereas Inventions V, X, XI, and XIV are drawn to different methods of

using a nucleic acid molecule. Invention II is unrelated to Inventions IV, VI, VIII, IX, and XI-XIII because Invention II is drawn to a nucleic acid whereas Inventions IV, VI, VIII IX, and XI-XIII are drawn to different methods of using polypeptides. Invention III is unrelated to Inventions V, VII-IX, XII, and XIV because Invention III is drawn to an antibody whereas Inventions V, VII-IX, XII, and XIV are drawn to different methods of using either a nucleic acid molecule or a polypeptide. Thus, the different inventions are drawn to distinct product and method inventions.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

9. Because these inventions are distinct for the reasons given above and the search required for a single group is not required for any other group, restriction for examination purposes as indicated is proper.

10. Furthermore, the application contains claims drawn to different nucleic acid or amino acid sequences (SEQ ID NOS: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26). Each individual sequence represents a structural and functionally distinct entity that is capable of supporting a separate patent. The search and consideration of more than a single sequence constitutes an undue search burden on the office, given the ever-increasing size of the database.

Applicant is advised that a reply to this requirement must include an identification of a nucleic acid or an amino acid sequence that is elected consonant with this requirement, and a listing of all claims readable thereon, including any

claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published

in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Elyabetz C. Kemmerer

Ruixiang Li
Examiner
March 25, 2002

ELIZABETH KEMMERER
PRIMARY EXAMINER